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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,144	08/21/2001	Glenn R. Larsen	GFN-5213CP6CN	9733

7590

08/10/2004

FINNEGAN, HENDERSON, FARABOW,
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1300 I STREET
WASHINGTON, DC 20005-3315

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,144

Applicant(s)

LARSEN ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,29-45 and 54-69 is/are pending in the application.
4a) Of the above claim(s) 1-20,29-45 and 54-57 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 58-69 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 12 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/02,6/03.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV in the reply filed on 20 May 2004 is acknowledged. The traversal is on the ground(s) that no separate searches are required. This is not found persuasive because the nucleic acids and proteins require searches of entirely different databases and thus the searches are different. The protein claims are broader in scope than the proteins used either of the groups drawn to methods. Thus the searches are different. The methods of Group IV require consideration of literature relevant to the process of inflammation as well as the diseases newly added by Applicant's amendment that is not required for a search of Group III. The methods of Group III require a search of other selectin proteins that is not required for group IV. Thus the searches are separate.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-20, 29-45, and 54-69 are pending in this application. Claims 1-20, 29-45, and 54-57 are withdrawn from consideration as being drawn to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities: Application number 08/713556 has now issued as U.S. patent 6,277,975. The specification should be updated accordingly.

There are sequences on p. 10, line 4, p. 11, lines 14-15, p. 13, lines 9-10, that require sequence identifiers. In addition, the sequences in figure 30 should be identified by sequence identifiers in the Brief Description of the Drawings.

The use of the trademarks MAXBAC (p. 19, line 31), SEPHAROSE (p. 21, lines 13 and 25) and En3HANCE (p. 43, line 34) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The claims are drawn to methods treating diseases of which inflammation is a component using soluble PSGL or fusion proteins thereof. There is no guidance in the specification to

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indicate that these soluble forms are capable of blocking the interaction of leukocytes with endothelial cells, as would be required to inhibit inflammation. All that is concluded is that the peptides comprising region 42-60 can bind to P-selectin and interfere with the binding of this protein to PSGL-1 (p. 49, lines 25-30, example 14, pp. 56-57). There is no guidance, *in vitro* or *in vivo*, to indicate that this interaction is sufficient to inhibit leukocyte/endothelial cell interaction. The art teaches that such inhibition is problematic and not a predictable outcome. Ulbrich et al. (Trends in Pharmacology, 2003, pp. 640-647) teaches that agents that affect selectin binding that appeared promising did not in fact provide any therapeutic effect (p. 642, column 2). In particular, Ulbrich et al. teaches that a fusion protein of PSGL-1 failed in clinical trials (p. 642, table 1, and p. 644, column 1). Furthermore, the claims are drawn not to inhibition of inflammation, but to treatment of diseases that involve inflammation. Even were the specification to provide guidance sufficient to allow the artisan to inhibit inflammation, this would not be sufficient direction as to how diseases such as myocardial infarction, infection, metastasis, transplant rejection, thrombosis, or other diseases of which inflammation is only one component could be treated. What would be treated would be the common process of inflammation that results from the disease.

Thus, because the claims are broadly drawn to encompass far more than the inhibition of inflammation, the specification provides no guidance other than protein-binding assays, and the art teaches that the success of this approach is unpredictable, it would require undue experimentation for the artisan to practice the invention.

NO CLAIM IS ALLOWED.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
6 August 2004


JANET ANDRES
PRIMARY EXAMINER